

## ASHBY & GEDDES

ATTORNEYS AND COUNSELLORS AT LAW  
222 DELAWARE AVENUE

P. O. BOX 1150

WILMINGTON, DELAWARE 19899

TELEPHONE  
302-654-1888

FACSIMILE  
302-654-2067

May 8, 2006

The Honorable Kent A. Jordan  
United States District Court  
844 King Street  
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: In re '318 Patent Infringement Litigation,  
Civil Action No. 05-356-KAJ (consolidated)

Dear Judge Jordan:

Pursuant to paragraph 8 of the Revised Scheduling Order (D.I. 81), Plaintiffs hereby submit this interim status report on the nature of the matters in issue and the progress of discovery to date. Pursuant to paragraph 9 of the Revised Scheduling Order, a telephone conference with the Court is scheduled for Monday, May 15, 2006, at 4:30 p.m. EDT, to discuss this matter.

Preliminarily we note that the parties had planned a *joint* filing, but we found that we have sharply differing views on what this interim report should contain, which caused us considerable difficulty in trying to agree on the wording of a joint letter. Given the press of time, the number of parties involved, and the number of attorneys who would need to be consulted regarding further revisions, Plaintiffs and Defendants are submitting separate versions. We respectfully request the Court's indulgence and understanding if Your Honor's preference would have been to receive a single joint submission.

### Nature of Matters in Issue

As the Court knows, this case has arisen out of Defendants' desire to make a generic copy of Plaintiffs' Razadyne® Alzheimer's treatment drug product. After Defendants filed Abbreviated New Drug Applications (ANDAs) to obtain regulatory approval to do so, Plaintiffs sued them for infringing the claims of U.S. Patent No. 4,663,318 ("the '318 patent") under the Hatch-Waxman law. Currently, Plaintiffs assert two claims (nos. 1 and 4) of the '318 patent, which expires on December 14, 2008.

Plaintiffs originally filed seven separate patent infringement lawsuits against thirteen individual Defendants, alleging infringement of the '318 patent. These cases were consolidated in October 2005. (D.I. 29). In response to Plaintiffs' Complaint, Defendants asserted counterclaims for declaratory judgment of noninfringement and invalidity. Defendants later filed a Stipulation Not to Contest Infringement in December 2005, (D.I. 49), and as such only

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Defendants' invalidity affirmative defenses and counterclaims are currently pending. The Court further dismissed Plaintiffs' claim for willful infringement in March 2006. (D.I. 132). Just recently, Plaintiffs and Defendant Par stipulated to Par's dismissal from this litigation, while Plaintiffs and Defendant Purepac stipulated to a stay of the litigation as to Purepac. (D.I. 174; D.I. 177).

### **Status of Discovery**

According to the Revised Scheduling Order, party fact discovery closes on June 30, 2006, and non-party fact discovery closes on July 7, 2006. The scope of discovery in this case has been narrowed by Court Order and by the parties' agreement on certain issues. Specifically, Plaintiffs have agreed not to pursue discovery (both written and oral) on the issues of infringement (in light of the Stipulation Not to Contest Infringement), willfulness (in light of the Court's Order of March 3, 2006), and products outside the scope of the galantamine products that are the subject of each particular Defendants' Abbreviated New Drug. Plaintiffs have made clear, however, their intention to introduce evidence related to the "failure of others" objective consideration of nonobviousness, and have further made clear that they will resist any attempt by defendants to introduce evidence on that subject that is not produced as part of this agreement. In turn, Defendants have agreed not to pursue discovery from Plaintiffs concerning Plaintiffs' products other than the Razadyne®/Reminyl® product that is the subject of Plaintiffs' New Drug Application at issue here. The parties also are negotiating various proposed stipulations recently offered by Plaintiffs concerning discovery issues.

In sum, to date, the parties have propounded and responded to written discovery, including interrogatories, requests for production of documents, and requests for admission, and have produced documents in response to document requests. The parties also have conducted depositions. Specifics about each of these issues follows:

### **Written Discovery and Document Production**

Both sides have exchanged written discovery requests (including interrogatories, requests for admission, and document requests) and objections and responses thereto. On April 17, 2006, Plaintiffs issued a second set of interrogatories to Defendants. Defendants' responses to those interrogatories are due on May 17, 2006. Defendants Teva and Dr. Reddy's served additional interrogatories on Plaintiffs on April 21, and April 24, 2006. Plaintiffs' responses to those interrogatories are due on May 22, and May 25, 2006, respectively.

In mid-April, Defendants Barr, Teva, and Mylan supplemented their answers to Plaintiffs' first set of interrogatories on the issue of the bases for Defendants' invalidity claims. Defendant Alphapharm supplemented its interrogatory answer on invalidity on May 5, 2006. Defendants Barr, Dr. Reddy's, Mylan, and Alphapharm believe that they have completed their document productions (an assessment with which plaintiffs disagree), although, depending upon the outcome of negotiations regarding stipulations recently offered by Plaintiffs concerning discovery issues, Defendants may end up having to produce additional documents in any event.<sup>1</sup>

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<sup>1</sup> Alphapharm and Plaintiffs also are discussing the status of Alphapharm's production.

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Defendants and Plaintiffs also have exchanged privilege logs. The parties anticipate discussing each other's privilege logs in upcoming correspondence.

In March 2006, Plaintiffs advised Defendants that they would supplement their interrogatory answers concerning claim construction and the objective considerations of nonobviousness, and later advised that they also would supplement their responses concerning conception, reduction to practice and first offer for sale, publication and public use issues. Plaintiffs anticipate doing so before the May 15 status conference.

### **Depositions**

Plaintiffs and Defendants have taken several depositions and have noticed several other depositions. The schedule requires the parties to complete all party depositions by June 30, 2006, and non-party depositions by July 7, 2006.

In late December 2005 to early January 2006, Defendants noticed the depositions of the '318 patent inventor, Dr. Bonnie Davis, the inventor's husband, Dr. Kenneth Davis, and the prosecuting attorney for the '318 patent, Mr. John Richards, as well as a Rule 30(b)(6) deposition of Ladas & Parry, Mr. John Richards' law firm. Defendants took those depositions in early February 2006.

In early April 2006, Defendants took the deposition of third-party fact witness Dr. Joseph Coyle. Defendants also have issued subpoenas to third parties Mt. Sinai and Dr. Berger-Sweeney. Dr. Berger-Sweeney's deposition is scheduled for June 6, 2006, and the Mt. Sinai deposition has not been scheduled (and Defendants' recent correspondence indicates that a deposition may not be necessary). Additionally, Defendants are considering pursuing one or two additional third-party depositions, including Shire Pharmaceuticals, before the close of non-party discovery on July 7, 2006.

On February 21, 2006, Plaintiffs served three Rule 30(b)(6) deposition notices on each of the defendants and scheduled those depositions to begin in mid-March. We will not burden the Court by repeating the difficulties we encountered with that deposition effort, as those details already are set forth in the two motions to compel filed by Plaintiffs.

In mid-April, Plaintiffs began three Rule 30(b)(6) depositions of Defendants. As the Court is aware, one of those depositions (of Mylan) had to be continued because Mylan's designee was not prepared adequately on the noticed topics, and because Mylan's counsel engaged in improper instructions. Plaintiffs believe that similar infirmities exist in the Barr deposition from April 18, and the parties conducted a meet-and-confer on May 5 to attempt to resolve a dispute concerning that deposition. Plaintiffs believe that Barr should have to bring its designee back to complete his testimony (for one-half day), and Barr is considering that request (having conceded that the witness was not prepared when it offered to bring the deponent back for a shorter time).

Plaintiffs are taking the remaining Rule 30(b)(6) depositions of Defendants on or before May 19, 2006. While Plaintiffs had hoped to complete these depositions sooner, Mylan was

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unwilling to make Mr. Harper available for deposition until after May 12, and the earliest date on which Dr. Reddy's was willing to produce its witness designee was May 19. Both those positions are contrary to the Court's Order that Defendants produce their witnesses in time for the Rule 30(b)(6) depositions to be completed by May 12.

Defendants have proffered the bulk of their witnesses to be deposed during the last few days before the May 12 cut-off, requiring us to take eight depositions during the period from May 9 to May 12, and also have produced thousands of pages of highly relevant discovery within a week of those depositions (and in at least one case, within 24 hours of the deposition). Plaintiffs are working hard to overcome the prejudice caused by Defendants' tactics, and we therefore have not yet sought the Court's assistance, but we may have to do so if the remaining witnesses are as ill-prepared as the Mylan and Barr witnesses, and/or if the Defendants continue to produce documents on the eve of depositions.

Plaintiffs also are pursuing depositions of third-parties Cheryl Blume, Pharmaceutical Development Group ("PDG"), and Somerset. The depositions of Dr. Blume and PDG are currently scheduled for May 10, 2006. The parties are working to schedule a mutually convenient date for third-party Somerset. On April 28, 2006, Plaintiffs filed a stipulated motion to issue letters of request for international judicial assistance seeking the deposition and documents of Boehringer Ingelheim GMBH and Co. KG in Germany.

We look forward to discussing these issues with Your Honor on May 15, 2006.

Respectfully,

*/s/ Steven J. Balick*

Steven J. Balick (I.D. # 2114)

SJB/dmf  
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cc: George F. Pappas, Esquire (via electronic mail)  
Josy W. Ingersoll, Esquire (via electronic mail)  
Edward C. Donovan, Esquire (via electronic mail)  
Mary B. Matterer, Esquire (via electronic mail)  
William A. Rakoczy, Esquire (via electronic mail)  
Richard L. Horwitz, Esquire (via electronic mail)  
Stuart D. Sender, Esquire (via electronic mail)  
John C. Phillips, Jr., Esquire (via electronic mail)  
Lynn M. Ulrich, Esquire (via electronic mail)  
Frederick L. Cottrell, III, Esquire (via electronic mail)  
Alan H. Bernstein, Esquire (via electronic mail)